SmartPump® Tourniquet System

Dual Channel Tourniquet Pump

REF 5920-011-000

stryker®

Instructions For Use

R_X ONLY

US Patents 6,051,016; 6,475,228; 6,605,103
Additional US and foreign patents pending

Software Version
1.3x

Table of Contents

PAGE

User/Patient Safety **5**

Indications *5*

Contraindications *6*

Possible Adverse Effects *6*

Precautions for Use *7*

Environment and Placement *7*

1 Introduction **8**

System Overview *8*

Features **9**

Convenient Preparation 9
Ease of Operation 9
Continuous, Real-time Monitoring 9
Accessory Information* 9

Power Options *10*
AC Power 10
Internal Battery 10
Low Battery Power Alarms 11
Maintaining Internal Battery Charge 11

2 Control Panel and Display **12**

Control Buttons *13*

Display Screen *15*

Display Indicators *16*
Status Indicators 16
Alarm Indicators 16

3 Preparing for Use **17**

Mounting the SmartPump *17*

Power Requirements *18*

Initial Set-up *18*

Default Parameters *19*
Procedure Timer 19
Target Pressure 19

Changing Default Time and Pressure Settings *20*

4 General Use Procedure **21**

Connect the Cuff To Fill Line Connector *21*

Turn On the SmartPump *22*

Setting Timer and Target Pressure *23*

Time Display Format *24*

Alarm Volume Adjustment *24*

Default Display Viewing Preferences *24*

Setting Time and Date *26*

Cuff Inflation *28*
Intravenous Regional Anesthesia (IVRA) Lock 28
To Inflate a Cuff 28
Cuff Pressure Gauge 29

Monitor Time and Pressure *29*

Cuff Deflation *33*

Tourniquet Report Printer *34*

Bier Block Procedure *35*

Responding to Alarms and Service Codes *36*

Service Codes *36*

Using the SmartPump's Backup Capability *37*

5 Cleaning and Maintenance **39**

Cleaning Recommendations *39*

Periodic Maintenance *40*

Annual Maintenance Checklist *43*

6 Service Code Summary **46**

7 Specifications **47**

User/Patient Safety

WARNINGS*:*

This manual explains how to use the Stryker SmartPump® tourniquet system. Failure to follow the conditions of use set forth below shall absolve Stryker from any responsibility for the safety, reliability, and performance of this equipment:

- Federal law restricts the sale of this device. It may be sold only by or on the order of a physician.
- Only qualified medical personnel may use the SmartPump.
- SmartPump users should read the *Instructions For Use* prior to operation.
- To reduce the risk of electrical shock, DO NOT open the enclosure. Refer service to qualified service personnel.
- Only personnel trained and/or authorized by Stryker may perform adjustments, modifications, or repairs to this equipment.
- The SmartPump must be used, maintained and cleaned in accordance with these *Instructions For Use*.

Indications

A tourniquet is indicated when it is necessary to reduce blood flow and/or when greater visualization of the operating field is imperative or desired. It is designed to temporarily occlude or decrease blood flow in a patient's extremities during surgical procedures of those extremities and is not a substitute for proper hemostasis. Typical procedures include:

- Arthroscopy
- Tendon repair
- Total wrist joint repair
- Knee joint replacement
- Finger joint replacement
- Nerve repair
- Bone grafts

And other surgeries of the extremities identified by your institution requiring temporary occlusion of blood flow.

Contraindications

A tourniquet is not suitable for ligatures or cauterization to stop hemorrhages and should never be applied without consideration of the local anatomy. The Stryker SmartPump and associated tourniquet cuff is contraindicated for use on the torso.

Tourniquets are contraindicated for use on patients exhibiting unusual or complicated neurological or vascular problems of the extremities such as arteriovascular impairment, phlebitis, infection, uncontrolled diabetes, and/or other associated problems.

Current medical literature lists the following as possible contraindications:

- Compromised vascular circulation
- Severe scar tissue in cuff zone
- Mellitus
- Open leg fractures
- Post traumatic lengthy reconstruction
- Severe crushing injuries
- Elbow surgery (associated with excessive swelling)
- Severe hypertension
- Skin grafts in which bleeding must be readily distinguished
- Presence of sickle cell disease or clotting disorder

All final decisions regarding use of a tourniquet are the responsibility of the attending physician.

Possible Adverse Effects

WARNING*:* Excessive pressure or prolonged application could potentially cause:

- Vascular complications
- Neuromuscular or neurological injuries
- Tourniquet pain
- Ischemia
- Venous emboli or thromboembolism
- Blood vessel trauma
- Reperfusion problems and arterial occlusion
- Mild, aching pain may develop in the limb
- Stiffness, weakness, reactive hyperemia, and skin discoloration
- Death, specific to the Bier Block procedure

Precautions for Use

Extreme care must be taken when using tourniquets. Minimum cuff pressure and application time should be used. Monitor time and pressure throughout the procedure as injury may occur.

WARNINGS:

- Disconnect the deflated cuff from the fill line connector when a procedure is completed. Disconnecting a deflated cuff manages potential risks by: (1) eliminating the risk of injury should a user unintentionally re-inflate a deflated, unmonitored cuff and (2) providing confirmation that the cuff deflation sequence has been implemented and completed. Failure to comply may result in patient injury.

- At the end of a procedure, as soon as the tourniquet pressure is released, remove the cuff, sleeve and other underlying materials, as the slightest impedance of venous return may lead to congestion and pooling of blood in the operative field. Failure to comply may result in patient injury.

Follow guidelines developed by your institution regarding standards of practice for tourniquet use. Failure to follow instructions could result in possible medical complications.

Published tourniquet guidelines and training programs developed by the Association of periOperative Registered Nurses (AORN) provide valuable references and resources to establish and update guidelines.

The AORN *Recommended Practices for Use of The Pneumatic Tourniquet* is available online. Originally published in the *AORN Journal* and revised in December 1998, it is included in the *AORN 2000 Standards, Recommended Practices, and Guidelines*.

AORN's web address is www.aorn.org. The AORN mailing address is 2170 South Parker Rd, Suite 300, Denver, CO 80231.

Environment and Placement

WARNINGS:

- The SmartPump is designed for use in a non-sterile zone of a surgical operating room. The SmartPump must be placed outside the patient zone, 6 feet [1.83 m] horizontally 8 feet [2.5 m] vertically.
- For optimal use, the SmartPump, including the roll stand with pole, must be positioned and installed according to the instructions herein.
- Use only hospital grade line cord connected to a hospital grade grounded receptacle.
- Ensure power cord is away from personnel traffic and areas of water or liquids.
- DO NOT place the SmartPump on an unstable cart, stand, or table. Recommend using the Stryker Roll Stand with pole REF 5920-013-000.
- DO NOT use this equipment in the presence of a mixture consisting of flammable anesthetic and air or oxygen or nitrous oxide.

1 Introduction

System Overview

The SmartPump is a dual channel tourniquet pump. It is designed for use by qualified medical personnel to temporarily impede blood flow in a patient's extremity in order to create a blood-free surgical zone.

Its dual channel design supports single cuff, bilateral and Bier Block procedures, and allows for simultaneous surgery of both an upper and lower limb. Each cuff's unique pressure and time settings are displayed, controlled, and monitored independently. The SmartPump uses single port cuffs.

The built-in serial interface port supports its optional Stryker Tourniquet Report Printer and enables Clinical Information System (CIS) connectivity.

The two channels are identified on the SmartPump's display as 'Cuff 1' and 'Cuff 2.' The cuff connection ports are identified similarly.

Cuff 1 may be referred to as the 'Main Cuff' and Cuff 2 as the 'Second Cuff.'

The SmartPump is shown with the recommended Stryker roll stand and cuff basket. The optional printer, printer tray and power cord organizer mounted below the basket are also shown.

Features

Convenient Preparation

- The internal battery is charged automatically whenever the SmartPump is plugged into an AC power source. The internal battery is recharged to approximately 80% level within one hour.
- The fully charged internal battery provides five hours of uninterrupted power. However, internal battery power is a safety feature and is to be used as a back up only. Always connect the SmartPump to an AC power source for normal operation.
- Battery 'saver' technology keeps the internal battery charged. If the SmartPump is fully charged, then left 'OFF(standby)' and unplugged, the internal battery is kept charged for up to 30 days.
- The SmartPump is center mounted to its recommended Stryker roll stand with pole.
- Fill lines are attached to the positive locking connectors located at the bottom corners of the SmartPump.
- At start-up, the SmartPump performs a self-test automatically and tests the pneumatic, pressure, display, battery, and processor systems. The SmartPump will alert the user via alarms, indicators and the display of error codes to assist in troubleshooting.

Ease of Operation

- The procedure timer and cuff target pressure may be set using simple, intuitive steps. Control buttons are clearly identified.
- Inflation is initiated by pressing the **Inflate** button.
- Deflation is initiated by pressing and holding the **Deflate** button for 1.5 seconds.

Continuous, Real-time Monitoring

- The large, bright, backlit LCD display shows total elapsed cuff inflation time and cuff pressure (mmHg). The displayed time format is user selectable: minutes or hours and minutes.
- Audible control alarms and flashing graphical symbols identify conditions requiring attention.

Accessory Information*

Description	REF
Roll Stand with Pole	5920-013-000
Tubing, Stockinettes, Fill Lines, and Adapters	5920-xxx-xxx Series
Disposable Tourniquet Cuffs	5921-xxx-xxx Series
Non-sterile Reusable Tourniquet Cuffs	5922-xxx-xxx Series

*Contact your Stryker sales representative for a complete list of accessories.

Power Options

AC Power

The Smart Pump's primary power source is AC power. As a safety feature, the SmartPump's internal battery provides an alterative (back up) power source if AC power is lost.

Always connect the SmartPump to an AC power source for normal operation.

Internal Battery

The SmartPump's internal battery automatically provides back-up power if AC power is interrupted. The internal battery when fully charged supports up to five hours of operation.

If, at initial start-up, the SmartPump is not plugged into AC power, the following occurs:

- **no AC** is displayed on the lower left of the LCD.
- The **Alarm Indicator Mute** button flashes red.

Pressing the **Alarm Indicator Mute** button within 30 seconds of initial start-up will cancel the alarm. In this mode, the **Alarm Indicator Mute** button will return to green, the **no AC** indicator will remain illuminated and the battery symbol will indicate the amount of battery charge.

NOTE: If, at initial start-up, there is no AC present and the **Alarm Indicator Mute** button is not pressed within 30 seconds, the SmartPump will return to its 'OFF(standby)' mode automatically. This feature prevents the SmartPump from unintentionally being used in a (back up) battery mode and prevents accidental battery discharge during transport and storage.

If AC power is interrupted during normal use, the SmartPump will use its internal battery automatically. Press the **Alarm Indicator Mute** button to acknowledge the change in power source. The **Alarm Indicator Mute** button returns to green.

When AC power is restored, the SmartPump will return to its normal AC operation automatically.

When the SmartPump is unplugged and turned 'OFF(standby),' it conserves its internal battery automatically using a power conservation mode. If fully charged, the internal battery is kept charged for up to 750 hours.

Low Battery Power Alarms

If a 'low battery' alarm condition occurs, connect the SmartPump to AC power as soon as possible. If AC power is unavailable and the internal battery becomes fully discharged, the SmartPump will maintain cuff pressure. Manual cuff deflation is required.

- If 30 minutes of internal battery operating time remain, the following will occur: an audible alarm, the **Alarm Indicator Mute** button will flash red and the battery charge icon will blink. The alarm may be muted for 15 minutes.
- If 15 minutes of internal battery operating time remain, an audible alarm will occur. The alarm may be muted for one minute, indicating the battery is 'minutes' from full discharge.

Maintaining Internal Battery Charge

When the SmartPump is plugged into AC power, its internal battery is charging automatically.

The SmartPump control panel indicates battery-charging status as follows:

Battery Charging Symbol: The segments of this symbol illuminates sequentially and repetitively while the internal battery is being charged. This occurs when the SmartPump is connected to an AC power source. Once the internal battery is fully charged, all of the segments are lit.

Battery Power Symbol: The segments of the battery power symbol are lit to indicate the level of battery charge during internal battery operation. For example, three segments lit indicate a charge level of approximately 80%.

AC Power LED Indicator: Illuminated green whenever AC power is applied to the unit.

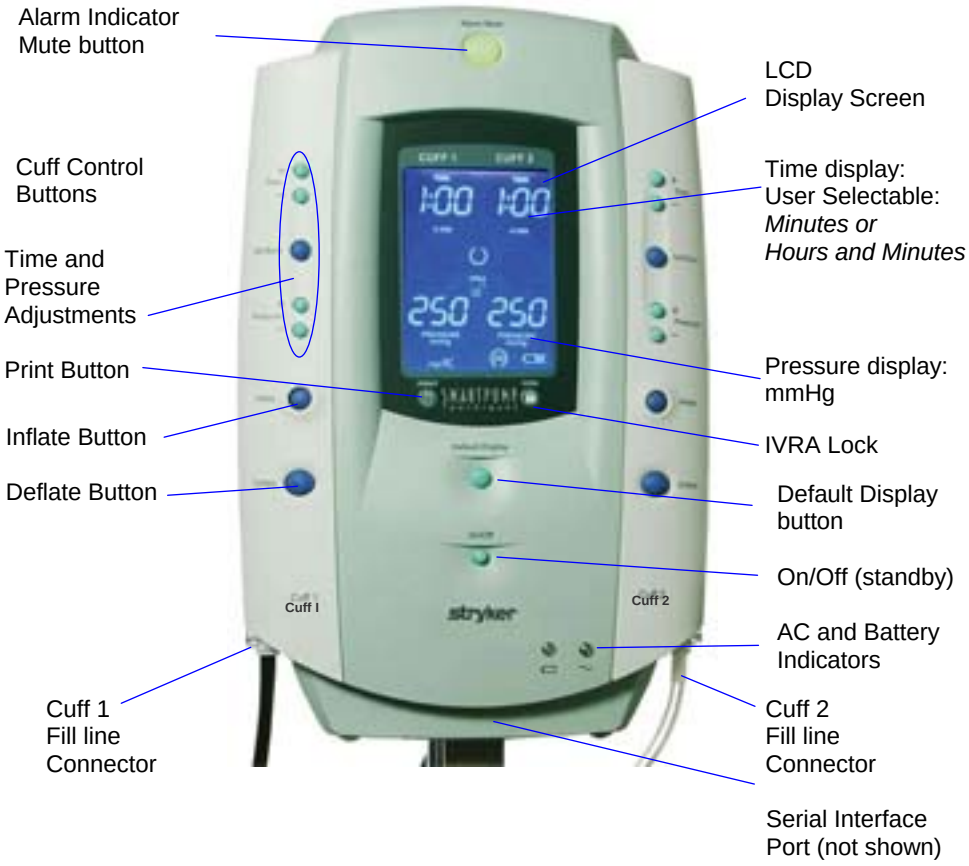
Battery Charge LED Indicator: Indicates battery charge status. The indicator operates when connected to AC power and the SmartPump is on or off.

- **Green (steady):** internal battery is fully charged, in trickle or slow charge mode.
- **Yellow (blink):** internal battery is in fast charge mode and may require one hour to reach an 80% charge level.
- **No Light:** internal battery is not charging; AC power may not be present. if AC power is present, there may be battery charge circuit failure or internal battery failure.

2 Control Panel and Display

This section reviews the SmartPump's interfaces, control panel layout, display screen functions, and icons.

The control panel is the user's interface to control, adjust, and set the following: Procedure Timer and Cuff Pressure, Inflation, Deflation, and Default Display. Cuff pressure and elapsed cuff time are displayed in real-time.



Control Buttons

Button	Explanation
	♦ Turn **ON** by pressing, then releasing the **ON/OFF** (standby) button. ♦ Turn **OFF** by pressing and holding the **ON/OFF** (standby) button for 1.5 seconds (safety pause).
	WARNING: Turning **OFF** the SmartPump while cuffs are inflated will deflate the cuffs and total elapsed time information will be lost.
SET/SAVE	**SET/SAVE** 1. Press the **Set/Save** button to initiate a change of the TIME and/or target PRESSURE for the corresponding cuff. The display will blink after the **Set/Save** button is pressed. 2. Press the **Set/Save** button again to save new time or pressure values.
+ **TIME** **-**	**TIME Increase/Decrease** (located above the **Set/Save** button) After pressing the **Set/Save** button**,** press these buttons to increase (**+**) or decrease (**-**) the inflation time for the selected cuff. Each button press changes the time value in 5-minute increments (1-minute increments within the 1 to 15 minute time range). The numeric display changes accordingly.
+ **PRESSURE** **-**	**PRESSURE Increase/Decrease** (located below the **Set/Save** button) After pressing **Set/Save** button**,** press these buttons to increase (**+**) or decrease (**-**) the inflation pressure for the selected cuff. Each button press changes the pressure value in 5 mmHg increments. The numeric display changes accordingly.
INFLATE	**INFLATE** Press the **INFLATE** button of the corresponding cuff to inflate the cuff to its target pressure. If a cuff is deflated during a procedure, press the **Inflate** button to return to the set pressure. The **Timer** stops during the period of a deflation and resumes accumulating total 'cuff time' upon reinflation.

DEFLATE

Press and hold the **Deflate** button for 1.5 seconds (safety pause) to initiate deflation. When deflation begins and after it is completed, the Deflation icon appears next to the cuff pressure gauge.

The tourniquet time monitor will stop accumulating time and display the total inflated 'cuff time.'

INFLATE

NOTE: To interrupt a deflation instantly, press the **Inflate** button. Re-inflation will commence immediately. The timer is restarted to accumulate additional elapsed 'cuff time.'

DEFAULT DISPLAY

At the end of a procedure and after deflation has occurred, press the **Default Display** button to clear and reset the SmartPump to its default time and pressure settings.

The **Default Display** button is also used to set new default time and pressure settings for preferred practice settings. See *Changing Default Time and Pressure Settings*.

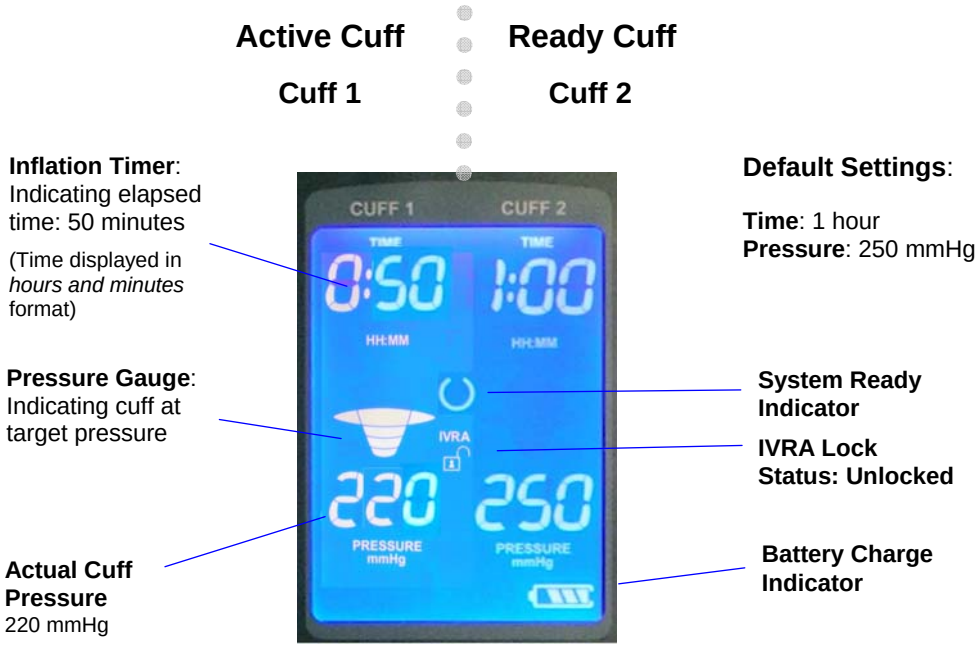
ALARM INDICATOR MUTE BUTTON

Indicator button illuminates green when the SmartPump is operating normally.

Indicator button flashes red when the SmartPump is in an alarm condition. Press the **Alarm Indicator Mute** button to mute the audible alarm. Correct the alarm condition to restore the indicator button to green.

Display Screen

Areas of the SmartPump display screen are illustrated below.



See *Display Indicators*.

Display Indicators

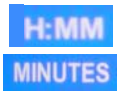
Status Indicators

Default Display: Illuminated when the time and pressure are set for the default target values.

Ready: All components are functioning normally and the unit is ready to use.

Battery Charge Status: Indicates if battery is charging (bars light sequentially) or battery charge level (when running from battery).

IVRA Lock: Indicates whether IVRA is locked or unlocked. This control provides accidental cuff/bladder deflation protection.



H: MM or **MINUTES:** Indicates time format in use.

Deflation: Indicates corresponding cuff is deflating or deflated.

Alarm Indicators

Service Required: When the SmartPump detects a condition that requires service, a service code with a wrench is displayed on the LCD and an audible alarm will occur. Note the code and call Stryker for assistance: 1-800-253-3210.

Caution: When an alarm is detected, the ‘Alert’ triangle is displayed, and either the time or pressure value will blink. DO NOT proceed until the alarm condition is resolved. Failure to comply may result in patient injury.

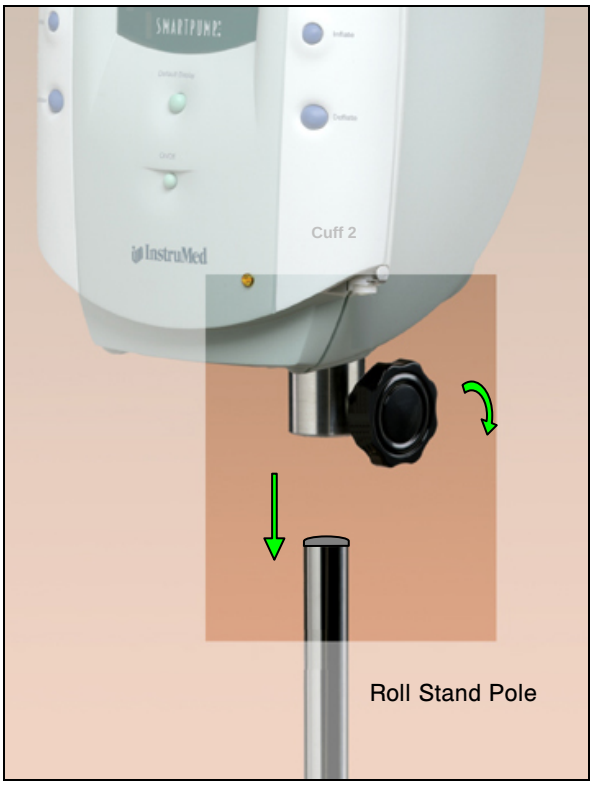
Audible Alarm: Indicates when the SmartPump is in an alarm condition and the audible alarm has been triggered.

Alarm Muted: Indicates when the SmartPump is in an alarm condition and the audible alarm has been muted.

3 Preparing for Use

Mounting the SmartPump

WARNING: Ensure the SmartPump is mounted on the roll stand pole securely. Failure to comply may result in user/patient injury.



1. Assemble roll stand. See *instructions for use* supplied with roll stand.
2. Gently lower the SmartPump onto the roll stand pole. Adjust the height of the SmartPump using the adjustment knob to facilitate access to the display and controls.
3. Tighten the knob to secure the SmartPump to the roll stand pole.

Power Requirements

The hospital-grade power cord shipped with the SmartPump is UL listed and configured for North American power sources. The SmartPump is configured for use with 120V, 10A, 60 Hz AC power.

Initial Set-up

The SmartPump is shipped with a fully charged battery, which provides a safety back up power source**.**

1. Mount the SmartPump onto the roll stand with pole.

WARNING: DO NOT connect any other electrical device into the power receptacle of the power cord organizer, except the SmartPump and Tourniquet Report Printer. Failure to comply may result in user/patient injury.

2. Connect the power cord between the SmartPump and the power cord organizer with power receptacle or a hospital-grade AC receptacle.

Press and release the **ON/OFF** (standby) button to initiate system power on and self-test. The self-test checks the pneumatic system, pressure, display, battery, and processors. Self-test errors are reported via service codes on the LCD display. See *Service Code Summary* section.

Upon successful completion of the system self-test, including battery charge level voltage test, the **Ready** indicator appears in the center of the display.

The **Battery Charging** indicator on the bottom right corner of the front enclosure indicates battery charge status. The system automatically begins charging the battery whenever it is connected to AC power.

The Battery Charge indicator segments on the lower right of the LCD illuminate sequentially when the battery is charging.

If the battery is not charged adequately, the alarm sounds and the **Battery** charge icon indicates low charge level.

Press and hold the **ON/OFF** (standby) button for 1.5 seconds to turn the unit off. Allow more charging time.

NOTE: The NiMH battery will attain approximately 80% of its rated capacity within one hour of charging.

Default Parameters

SmartPump factory preset default time and pressure settings are:

1. Elapsed Procedure Time: One hour
   (Displayed as: **1:00**)
2. Target Cuff Pressure: 250 mmHg
   (Displayed as: **250)**

Procedure Timer

The timer display shows elapsed procedure time.

The timer may be set to the desired cuff inflation time from a minimum of one minute. Timer adjustment may be made in one-minute increments from 1 to 15 minutes, and five minute increments from 15 to 240 minutes.

The Cuff time alarm is preset at the factory for one hour. This means that, if unchanged, the time setting for the Cuff is one hour. The **Timer's** alert will sound, the **Alarm Indicator Mute** button will flash red and the corresponding time display will flash when the preset total elapsed inflated cuff time has been reached.

NOTE: The SmartPump does **NOT** automatically deflate the cuff when the target time is reached. It maintains inflation until the **Deflate** button is pressed or the SmartPump is turned off.

Target Pressure

The default target pressure is preset to 250 mmHg at the factory. The default pressure may be adjusted and set between an operating range of 100 to 475 mmHg, in 5 mmHg increments.

Changing Default Time and Pressure Settings

To change the Default Time and/or Target Pressure:

1. If the unit is turned off, press the **ON/OFF** (standby) button to turn it on. Following self-test, it will enter the 'Ready' state.
2. Press the **Set/Save** button on the side requiring change. The corresponding time and pressure values will blink.
3. To change the default time, use the increase (+) or decrease (-) buttons. Each press adjusts the time in 5-minute increments (one-minute increments in the 1 to 15 minute time range). The numeric time display changes accordingly.
4. To change the default pressure, use the increase (+) or decrease (-) buttons. Each press adjusts the pressure in 5 mmHg increments, numeric pressure values change accordingly.
5. When the desired values are displayed, press the **Default Display** button to store the new values as the new default settings. The display stops blinking and the double-beep indicates the new values have been stored.

The **Ready** indicator reappears in the center of the display.

The **Default Display** indicator appears near the bottom of the display indicating that the default settings are being used.

NOTE: If the **Default Display** button is not pressed within five minutes of starting the adjustment process, the Set Mode is cancelled without changing the settings.

4 General Use Procedure

The basic steps required to initiate the inflation and deflation of a tourniquet cuff are summarized below:

NOTE: Prior to cuff inflation, the slight impeding affect caused by the presence of the un-inflated cuff and limb protection sleeve may inhibit venous return, causing slight intraoperative bleeding at the beginning of the procedure.

1. Turn unit on
2. Confirm default settings are correct *or*,
3. Set procedure timer and target cuff pressure
4. Position cuff on patient's limb
5. Connect cuff to fill line connector
6. When ready, press the **Inflate** button
7. Monitor cuff time and pressure during the procedure
8. Manage Timer and Pressure as necessary
9. Deflate the cuff and disconnect the cuff from fill line connector.

WARNING: At the end of a procedure, as soon as the tourniquet pressure is released, remove the cuff, sleeve and other underlying materials, as the slightest impedance of venous return may lead to congestion and pooling of blood in the operative field. Failure to comply may result in patient injury.

Connect the Cuff To Fill Line Connector

Fill Line Connector

Fill Line Connector

The cuffs are controlled by the corresponding sides of the SmartPump control panel.

Quick connect style fill line connectors are located on the bottom corners on the front of the SmartPump.

Turn On the SmartPump

Press the **ON/OFF** (standby) button to activate the SmartPump and initiate the self-test.

The software version (example: **1.10**) appears briefly at the bottom left of the display.

1.10

At the conclusion of a successful, self-test:

The default time and pressure values for both cuffs are displayed.

The **Ready** indicator appears in the center of the display.

The **Default Display** icon appears at the bottom of the display.

If the displayed Time and Cuff Pressure settings are acceptable, proceed with the cuff inflation by pressing the **Inflate** button.

If the self-test fails, the following occurs:

The **Alarm Indicator Mute Button** flashes red and the audible alarm sounds. Press the **Alarm Indicator Mute Button** to mute the unit.

WARNING indicators will appear on both sides of the display and a “wrench” icon will appear next to the service code, indicating service is required. DO NOT proceed until you resolve the alarm condition. Failure to comply may result in patient injury.

Note the code and call Stryker for assistance: 1-800-253-3210.

Setting Timer and Target Pressure

To adjust the cuff inflation timer or the target pressure, follow the instructions below. Newly set values will remain in effect until they are: (1) changed, (2) the **Default Display** button is pressed after deflation or, (3) the unit is turned off and restarted.

NOTE: A quick ***error-beep*** sounds if an inappropriate button press sequence is used. For example, if the (+) or (-) button is pressed before pressing **Set/Save,** the unit produces an ***error-beep*.**

1. Time and Pressure values may be changed when the SmartPump is in the 'Ready' mode or during active cuff inflation.

2. Press the **Set/Save** button on the side requiring change. The corresponding Time and Pressure values will blink.

3. *To change the set Time,* use the increase (+) or decrease (-) buttons. Each press adjusts the time in 5-minute increments (1-minute increments in the 1 to 15 minute time range). The numeric time display changes accordingly.

4. To change the set Pressure, use the increase (+) or decrease (-) buttons. Each button press adjusts the pressure in 5-mmHg increments, displayed numeric values change accordingly.

5. When the desired value is displayed, press the **Set/Save** button to implement the new settings. A confirmation ***double-beep*** indicates the new values are accepted. The blinking display returns to normal operation.

6. If a cuff is not inflated, the **Ready** indicator reappears in the center of the display screen. If settings are changed while a cuff is in use, the cuff Pressure and/or Time changes are real-time.

7. When using two cuffs, the cuffs are controlled separately.

Time Display Format

Change the Time Display format by pressing both Time (+) buttons simultaneously while the SmartPump is in the 'ready' mode, with both cuffs deflated (not active). It is not possible to change the time format if a procedure is started.

If it is currently displaying H: MM (hours and minutes) it will automatically shift to Minutes and vice versa.

A Time Display format change remains in effect permanently until changed again.

Alarm Volume Adjustment

While pressing the **Alarm Indicator Mute Button**, press either the (+) or (-) buttons on the top left of the SmartPump to increase or decrease the alarm volume to a desired level. Alarm volume may be changed when the SmartPump is active or in the 'ready' mode.

Default Display Viewing Preferences

The SmartPump is preset to display each cuff default time and pressure setting continuously while in the 'ready' mode. When a single cuff is inflated, the other cuff's default settings remain displayed.

In a clinical environment, where single cuff procedures are predominant, the user may choose to 'minimize' the display of the unused cuff's default settings, as illustrated in figure B.

To minimize the Default Display, perform the following:

(1) With the SmartPump in the 'ready' mode (no cuffs inflated), press and hold the **Alarm Indicator Mute** button, then press the **Default Display** button. See figure A.

(2) The display will cycle twice, blinking one side, then the other. This confirms the selection of minimization. In this mode, when **either** cuff is inflated, the unused cuff's default settings will be minimized. See figure B.

(3) When in the 'Default Display Minimization Mode', minimized default settings may be viewed by:

a. Pressing the Default Display button, or

b. Locking the IVRA Lock, or

c. Pressing the **Inflate** button on the minimized side.

To restore the continuous display of the default settings, repeat step 1 above. The entire display will blink indicating the change in mode.

Figure A

Figure B

Setting Time and Date

The SmartPump's real-time clock tracks Time and Date. Time/Date is maintained by its internal battery.

NOTE: The real-time clock does not automatically adjust for daylight savings time changes.

To adjust Time and Date, the SmartPump must be in the 'ready' mode without an inflated cuff. It is not possible to change the Time or Date if a procedure is underway.

Button	Explanation
	1. Confirm the SmartPump is in the 'ready' mode. 2. Simultaneously press and hold **Set/Save** and **+ Time** buttons on the left side of the SmartPump for four seconds. Release both buttons. The current time value (HH: MM, 24 hour format) will appear in the bottom left corner of the LCD, with the hours value blinking.

For example, the hour's value is 12 (noon) (time is in 24-hour format).
12:34

3. ***Set the hours:*** Use the left side time increase (+) or decrease (-) buttons to adjust the hours setting.
4. Press **Set/Save** button to save the new hours setting. The minutes will blink. For example, the minute's value is 34. 12:34

5. ***Adjust minutes***: Use the left side time increase (+) or decrease (-) buttons to adjust the minutes setting.
6. Press the **Set/Save** button to save the new minutes setting. The current calendar date will appear, with the month blinking, i.e., **12** (December). **12.06**
7. ***Set the month:*** Use the left side time increase (+) or decrease (-) buttons to set the month.
8. Press **Set/Save** to save the new month setting. The current calendar date will blink, i.e., the date is the **6**th. **12.06**
9. ***Set calendar date:*** Use the left side time increase (+) or decrease (-) buttons to set the date.
10. Press **Set/Save** to save the new date setting. The current calendar year will blink. For example, the year is **2006**
11. ***Set the year:*** Use the left side time increase (+) or decrease (-) buttons to set the year.
12. Press **Set/Save** to save the new time and date settings. The SmartPump will now return to the 'default display' mode.

Cuff Inflation

The individual channels for Cuff 1 and Cuff 2 operate independently. The SmartPump display screen displays real-time pressure values and total elapsed cuff inflation time for each cuff.

Intravenous Regional Anesthesia (IVRA) Lock

The Intravenous Regional Anesthesia (IVRA) Lock may be activated either prior to or after inflation. The lock prevents accidental deflation of an active cuff associated with a Bier Block procedure or the management of two cuffs involved in a bi-lateral procedure.

In its unlocked state, the IVRA Lock icon resembles an unlocked padlock. In a locked state, the icon changes to a locked padlock. See images below:

The IVRA (*lock, unlock*) button is below the LCD, on the right.
If, when attempting to deflate the second cuff with the IVRA Lock enabled, the SmartPump will produce an audible error-beep and the IVRA padlock will blink.

To Inflate a Cuff

Press the **Inflate** button on the selected side.

- The selected cuff is inflated to the target pressure.
- The SmartPump begins tracking and displaying the elapsed cuff time. The elapsed time appears at the top of the screen and is represented numerically and graphically.
- The cuff pressure is monitored on a real-time basis. The pressure is displayed numerically at the bottom of the screen.
- The graphic pressure gauge appears above the numeric pressure and graphically represents the status of the cuff.

Cuff Pressure Gauge

The pressure gauge displays the actual pressure in relation to the target pressure. Target pressure has been reached when the wide oval "mushroom" in the center of the gauge is illuminated. Pressure gauge illustrations below depict various states of target pressure.

Under Target **Target Pressure** **Over Target**

Monitor Time and Pressure

The SmartPump display screen provides the information needed to monitor the elapsed procedure time and the inflation pressure of the cuff(s) in use.

Time and/or pressure settings may be changed during a procedure. Immediately after changing the setting(s) and pressing the **Set/Save** button, the SmartPump adjusts the time and/or pressure to the new setting(s). See *Setting Timer and Cuff Pressure*.

When the Target Time Is Reached

Once the inflation timer has reached the target time set for the procedure, the following happens:

1. The **Alarm Indicator Mute** button flashes red, the 'Time' setting on the LCD blinks once per second and an audible alarm chimes 6 times – over 6 seconds. The audible chime then pauses 6 seconds and repeats the 6-beep sequence.

2. The alarm chime will continue indefinitely until (a) the **Alarm Indicator Mute** button is pressed, (b) additional time is added to the timer or (c) the cuff is deflated.

3. When the **Alarm Indicator Mute** button is pressed, the audible chime is silenced for 15 minutes. However, the time value on the LCD display will continue to blink once per second.

When the target time is reached, do one of the following:

- Deflate the cuff by pressing the **Deflate** button for 1.5 seconds, and if necessary, re-inflate the cuff.
- Press the **Alarm Indicator Mute** button to mute the alarm for 15 minutes. The Alarm light will continue to flash red. The SmartPump will continue to record and display the total elapsed cuff time.
- Add more time using the **Set**/**Save** button and (+) button. See *Setting Timer Cuff Pressure.*

NOTE: The SmartPump does not automatically deflate when the target time is reached. Deflation must be initiated by pressing the **Deflate** button.

Real-time Pressure Management and Alarms

The SmartPump maintains real-time cuff pressure within its normal operating parameters relative to the set target pressure automatically. Pressure variances are typically detected and corrected to the target pressure instantaneously, within two/tenths of a second.

Its pressure adjustment responses are sequenced to deliver optimal, progressive pressure compensation without causing overpressure fluctuations, unnecessary - frequent pressure adjustments or triggering false, transient pressure alarms. This enhances overall cuff pressure maintenance, while addressing the unique pressure dynamics associated with various size cuffs and their relatively low inflatable volumes.

After initial cuff inflation, the SmartPump compensates for minor changes in cuff pressure above or below the set target pressure automatically. Cuff pressure changes, within normal operating parameters and pressure compensation thresholds, may be caused by:

(a) Limb extension and contraction,

(b) Initial cuff conformity and tissue compression

(c) A leaking/damaged reusable cuff, leaking cuff O-ring, loose Luer connector, or fill line leak.

Intraoperative limb manipulation may cause the cuff to induce a momentarily, minor high and/or low-pressure fluctuation that the system detects and corrects automatically.

A momentary decrease in limb volume, associated with extension motions may cause the pneumatic system to sense low pressure, as the cuff's compressible target has become briefly 'smaller.' This type of minor, low-pressure activity is corrected precisely by the SmartPump's internal pressure reservoirs.

Momentary increases in pressure within the pneumatic circuit may also occur due to external compression of the cuff during limb contraction, which temporarily causes the limb to assume a 'larger' compressible volume. This type of momentary high-pressure is managed automatically and adjusted to target pressure instantaneously.

WARNING*:* Cuff and fill line leaks may cause regular, frequent cycling of valves accompanied by repeated or continuous pump motor activity refilling the internal pressure reservoir. This type of leak becomes problematic if the leak volume increases during the procedure, creating a leak rate, which cannot be compensated for by the SmartPump's maximum flow rate. Discard damaged reusable cuffs, replace damaged cuff O-rings and fill lines and use new, single use disposable cuffs. Failure to comply may result in patient injury.

Cuff pressure conditions which exceed those associated with normal operation and the responses reviewed previously, will trigger the SmartPump's audible alarm and visual alarms including the flashing red **Alarm Indicator Mute** button and blinking cuff pressure value(s). The SmartPump will continue to adjust pressure to the set target pressure while the audible alarm is muted. In a muted state, the pressure values continue to blink.

If automatic pressure adjustments do not resolve the low or high-pressure conditions within one second, the following occurs:

- The cuff pressure audible alarm sounds once a second.
- Low-pressure alarms are muted for 30 seconds by pressing the **Alarm Indicator Mute** button, with the exception of a minor low-pressure event.
- A minor low-pressure alarm is muted for 60 seconds. Minor low pressure is defined as a pressure value not more than 25 mmHg below target, for a period longer than one second.
- The **Alarm Indicator Mute** button will continue to flash red when the audible alarm is muted.
- Icons associated with the alarm condition will continue to blink until the condition is corrected.

When the correct pressure is restored, within tolerance, at the set target pressure, the alarm state is cleared automatically.

Cuff Deflation

A cuff may be deflated at any time during a procedure.

To deflate a cuff:

- Press the **Deflate** button for the selected cuff for 1.5 seconds.

As the cuff deflates, the following happens:

- The numeric pressure and gauge indicate a real-time pressure decrease. When the cuff pressure reaches zero, the numeric pressure display and the pressure gauge become blank.

- The **Deflation** indicator appears next to the pressure value on the relevant side of the display.

In its deflated (inactive) state, the SmartPump continues to monitor ambient air pressure. The SmartPump exhausts any ambient pressure that may be caused by cuff or patient movement automatically, prior to cuff removal.

WARNING: At the end of a procedure, as soon as the tourniquet cuff pressure is released, remove the cuff, sleeve and other underlying materials. The slightest impedance of venous return may lead to congestion and pooling of blood in the operative field. Failure to comply may result in patient injury.

The total elapsed cuff time remains displayed.

Prior to pressing the **Default Display** button, a deflated cuff may be re-inflated to the highest pressure used during the procedure by pressing the **Inflate** button. The **Timer** will restart and continue to accumulate inflated cuff time.

The most recent procedure's cuff time is cleared when the **Default Display** button is pressed.

NOTE: The **IVRA Lock** may be used to prevent accidental cuff deflation during Bier Block procedures. See *Intravenous Regional Anesthesia (IVRA) Lock* and *Bier Block Procedure*.

Tourniquet Report Printer

When connected to the optional SmartPump Tourniquet Report Printer, the SmartPump has the ability to print a tourniquet report, providing a summary of tourniquet activity.

This 2-inch by 3-inch report is printed on a self-adhesive label that easily attaches to the patient chart.

To print the report, press the **Print** button located below the LCD display on the unit's left side.

Procedure summary data is saved to a non-volatile memory that will preserve the data even if the SmartPump is turned off, AC power is removed or the internal battery is fully discharged.

Each time the SmartPump starts a new procedure, the previous procedure is fully erased and new data is accumulated.

Procedure summary data is preserved until either of the following events happen, which will cause the last procedure's summary data to be erased:

Default Display button is pressed and the **Inflate** button is pressed

-- or --

SmartPump is powered down, then restarted and the **Inflate** button is pressed.

See instructions for use supplied with the *SmartPump Tourniquet Report Printer*.

Bier Block Procedure

Follow your institution's standard Bier Block procedures.

WARNING: During a Bier Block or dual cuff procedure, confirm the status of the primary cuff before initiating a deflation. Failure to comply may result in patient injury.

The SmartPump will support a Bier Block cuff with its (Cuff 1) and (Cuff 2) tourniquet controls.

- Use of the **IVRA Lock** prevents accidental deflation of a cuff.

- To engage the **IVRA Lock,** press the **IVRA Lock** button. The **IVRA** padlock icon will change to the locked position.

1. Begin the procedure by sequencing the inflation and deflation of the Bier block cuffs according to your institution's standard practice.
2. When the procedure is completed, unlock the **IVRA Lock** to deflate the remaining Bier cuff, **or**
3. Reduce the cuff pressure in stages. Follow standard **Set**/**Save** pressure adjustment steps. See *Setting Timer and Cuff Pressure*.
4. When the incremental deflation sequence is complete, unlock the **IVRA Lock** and fully deflate the cuff.

NOTE: Press the **Inflate** button to interrupt a cuff deflation instantly or to return a cuff to the highest pressure used during the preceding procedure.

Responding to Alarms and Service Codes

When an Alarm event occurs, the following happens:

- The **Alarm Indicator Mute** button flashes red.
- An audible alarm sounds.
- The associated graphic or numeric will flash.
- When the target procedure time has been reached, the time display blinks.

Press the **Alarm Indicator Mute** button to silence the alarm. The audible **Time** alarm will remain muted for 15 minutes. Pressure alarms may be muted for 30 seconds or one minute depending on their severity.

Once the alarm is muted, the audible **Alarm** indicator is illuminated with a slash.

Correcting the alarm condition will reset the alarm system automatically.

Common alarms are typically corrected by:

(a) eliminating a leaking pneumatic connection or replacing a leaking cuff,
(b) adding time to the procedure Timer,
(c) charging a low battery, or
(d) connecting the SmartPump to an AC power source.

Service Codes

Service codes are listed in the *Service Code Summary* section. When the SmartPump detects a condition that requires service, a service code with a wrench is displayed and the SmartPump will alarm. Note the code and call Stryker for support at 1-800-253-3210.

Using the SmartPump's Backup Capability

Should one side (Cuff 1 or Cuff 2) become inoperative, the user may switch sides and continue operation.

The following steps summarize the techniques used to 'switch' a cuff from one side of the tourniquet pump to the other as 'backup' when an inflated (active) cuff is at risk and no alternative is available. This procedure should be used only when necessary. Adapt these guidelines to reflect your institution's protocols.

Prior to action, confirm all connections and cuffs are leak-free.

SINGLE TOURNIQUET CUFF

- During the initial inflation, if the tourniquet cuff cannot reach or maintain target cuff pressure, discontinue use.
- After inflation, if cuff pressure is at risk and/or tourniquet pump alarms cannot be resolved:
    1) Clamp-off the inflated cuff's fill line and remove it from the fill line connector of the SmartPump.
    2) Press the **Deflate** button on the failed side to clear its alarm state.
    3) Move the clamped fill line cuff to the other side of the SmartPump and insert it into the fill line connector.
    4) Press the **Inflate** button and release the clamp as the SmartPump takes control**.** This action may cause a momentary pressure alarm.
    5) Adjust the pressure and cuff timer as necessary.

WARNING: In the unlikely event of a complete SmartPump failure, such as the simultaneous loss of AC and battery power, the SmartPump is designed to close and lock its internal valves to protect an inflated cuff from unintended deflation. Deflate by manually disconnecting the cuff. Failure to comply may result in patient injury.

- During initial inflation, if the primary cuff cannot reach or maintain target pressure prior to anesthetic injection, discontinue use of the cuff.
- If, prior to deflation of the primary cuff, the second cuff cannot reach or maintain target pressure, do the following:

    1. Clamp-off the primary cuff to retain pressure, and disconnect the fill line. This action will cause the SmartPump to alarm.
    2. Connect the second cuff's fill line to the fill line connector of the primary cuff.
    3. The SmartPump will inflate the second cuff to the target pressure.
    4. After confirming the second cuff is at the target pressure, the clamped primary cuff may be released.
    5. Adjust the Pressure and Cuff Timer as necessary.

5 Cleaning and Maintenance

Cleaning Recommendations

Clean the SmartPump periodically using the following procedure:

CAUTIONS:

- DO NOT sterilize the SmartPump by any means including EtO, chemical disinfectant, or steam. Failure to comply may result in product damage.
- DO NOT use chlorine, ammonia, or iodine-based agents. Failure to comply may result in product damage.
- DO NOT allow water, detergent or any liquid to enter any button opening or electrical connector. Failure to comply may result in product damage.
- DO NOT use abrasive materials. Failure to comply may result in product damage, like scratching the LCD window.

1. Wipe the exterior surfaces with a soft cloth moistened with a mild detergent to clean the SmartPump.
2. Wipe the external surfaces with a clean cloth moistened with warm water to rinse the SmartPump.
3. Wipe the external surfaces with a soft cloth to dry the SmartPump.

Periodic Maintenance

The SmartPump should be checked annually for proper operation.

Required hardware and materials:

- Calibrated manometer (0 to 500 mmHg range)
- 10 foot fill line
- 15 inch to 24 inch Stryker Color Cuff for test purposes
- Y-connector to connect manometer to fill line when measuring pressure
- Soft clean cloth and cleaning agent (see *Cleaning Recommendations*).

NOTE: Test both the Cuff 1 and Cuff 2 sides of the SmartPump. Complete one side before attempting the other side.

Perform the following steps annually. These guidelines are not intended to replace inspection and checks that are independently developed and adopted by the end user's institution.

1. Examine the enclosure, all the connectors, the AC power cord and the fill line for damage, such as cracks, abrasion, or a damaged 'O' ring on the fill line connector. DO NOT use the equipment if damage is apparent.

2. Clean the SmartPump. See the *Cleaning Recommendations*.

3. Plug the SmartPump into AC power. Verify that the green AC power light on the front panel is lit.

4. Verify the internal battery charge light is either blinking yellow (fast charge mode), solid yellow (slow charge mode) or is solid green (trickle charge mode).

5. Allow the SmartPump's internal battery to charge fully. A complete charge should take no more than six hours. Charge time depends on how much the battery was discharged. When fully charged, the internal battery charge light will illuminate green.

6. Press and release the **ON**/**OFF** (standby) button on the front panel. During the startup sequence, the SmartPump's software version is displayed at the lower left of the LCD. Record the software version, along with the serial number, on the checklist form.

7. The SmartPump should now be at the 'ready' mode, with the default time and default pressure indicated. If the default values are not: 1:00 hour (60 minutes if using the Minutes time format) and 250 mmHg pressure, use the **Set/Save** button to adjust the settings, then proceed.

8. Remove AC power by unplugging the AC power cord. The two LEDs on the front panel (AC power and internal battery charge) should turn off. The SmartPump should remain operating, using the internal battery to provide power. The **Alarm Indicator Mute** button should flash red and the **no AC** message should appear on the lower left of the LCD. Press the **Alarm Indicator Mute** button to cause the **Alarm Indicator Mute** button to remain green.

9. Turn the unit off and then back on using the front panel **ON/OFF** (standby) button. The two LEDs on the front panel (AC power and battery charge) should be off. The unit will be operating using the internal battery for power. The **Alarm Indicator Mute** button should flash red and the **no AC** message should appear on the lower left of the LCD. Press the **Alarm Indicator Mute** button to cause the **Alarm Indicator Mute** button to stay solid green color.

10. Change the Time setting to 15 minutes. Press **Set/Save** button to save this new time setting.

11. Connect a 10-foot fill-line to the SmartPump. Connect a Y-connector to the end of the fill line. Connect a 15 inch to 24 inch size cuff to one branch of the Y-connector. Connect the manometer to the other branch of the Y-connector.

12. Turn the manometer on and zero the pressure value of the manometer. See the instructions for use supplied with the manometer.

13. Allow the cuff to lie flat on a smooth surface. Ensure the fastener does not restrict the cuff from filling to a 'tube' shape during the testing.

14. Confirm the pressure is set to 250 mmHg. Press the **Inflate** button and allow the pressure to stabilize for 5 seconds. The tube shape cuff may need a few seconds to stabilize its volume.

15. Record the displayed pressure and manometer pressure on the checklist.

16. Repeat steps 10 and 11 with the pressure set to 100 mmHg.
17. Repeat steps 10 and 11 with the pressure set to 475 mmHg.
18. Set the pressure to 300 mmHg.
19. Audibly monitor the SmartPump until the timer expires for at least 5 minutes. During this test, the air pump and valves may cycle occasionally, possibly once every minute or more, but not more frequently than once every 15 seconds. If the air pump cycles more frequently than once every 15 seconds, check the pneumatic connections, tubing and cuff for air leaks. The manometer pressure value should remain at 300 mmHg (± 2%) for the duration of this test.
20. Press the **Alarm Indicator Mute** button to silence the alarm when the timer expires. The indicator will continue to blink red.
21. Change the timer value to 30 minutes. The alarm should cancel and the **Alarm Indicator Mute** button should be illuminate green.
22. Press the **Deflate** button to deflate the cuff.
23. Press the **Inflate** button. The cuff should re-inflate to 350 mmHg for this test sequence.
24. Momentarily disconnect the fill line from the SmartPump. The alarm should sound and the **Alarm Indicator Mute** button should flash red, indicating a low-pressure pneumatic leak condition. Reconnect the fill line, and the cuff should re-inflate and the alarm should turn off automatically.
25. If you have a SmartPump Tourniquet Report Printer, connect it to the SmartPump. See the instructions for use supplied with the SmartPump *Tourniquet Report Printer*. Deflate the cuff, then press the **Print** button. The printer should print a label, summarizing the test steps and time and date of the testing, automatically. Verify the time and date values and adjust the SmartPump's time and date if necessary. Place this label on the checklist.
26. Sign and date the annual maintenance checklist.

Annual Maintenance Checklist

☐ PASS ☐ FAIL	**Model**	**REF 5920-011-000**
	Serial Number	_____
	Software Version	_____
	Date Tested	_____
	Tester	_____

VISUAL INSPECTION	☐ visual inspection for loose components, alignment of case and rubber handle	
BUTTON AND LED CHECKS	☐ all buttons functional ☐ all LCDs functional	
AC and BATTERY CHARGE INDICATORS	☐ AC indicator light ON when AC power present ☐ battery charge indicator shows battery charge status	
AC POWER ERROR	☐ **no AC** error message when AC power removed	
AC POWER FAIL AT START-UP	☐ Unit will alarm at start-up with no AC power (LCD message and **Alarm Indicator Mute** button red, no audible tones). Alarm may be cancelled (LCD message **no AC** remains).	
PRESSURE CALIBRATION **VERIFICATION**	**100 mmHg (± 4 mmHg)** Cuff 1 displayed _____ measured _____ Cuff 2 displayed _____ measured _____	**250 mmHg (± 5 mmHg)** Cuff 1 displayed _____ measured _____ Cuff 2 displayed _____ measured _____

	475 mmHg (± 9 mmHg) Cuff 1 displayed _____ measured _____ Cuff 2 displayed _____ measured _____	
300 mmHg LEAK TEST	☐ Infrequent (if any) valve and pump activity during 5 minute leak test	
TIMER TIMEOUT	Timer times out after time limit occurs indicated by: ☐ audible alarm ☐ **Alarm Indicator Mute** button flashes red ☐ blinking time indicator	
TIMER ALARM CANCEL	Timer alarm cancel indicated by: ☐ audible alarm stops ☐ **Alarm Indicator Mute** button flashes red ☐ blinking time indicator	
TIMER RESET	Increasing the timer value will reset the timer alarm to the normal state. Timer alarm reset indicated by: ☐ audible alarm stops ☐ **Alarm Indicator Mute** button is solid green ☐ time indicator stops blinking	
DEFLATE OPERATION INTERRUPTION	☐ cuff re-inflates to prior setting (350 mmHg) if deflation interrupted and deflates fully if deflation not interrupted	
LOW PRESSURE ALARM	☐ alarm is generated if fill line is disconnected to simulate a pneumatic leak	
TIME, DATE and SERIAL NUMBER SET CORRECTLY	☐ time of day correct ☐ date correct ☐ serial number matches serial number on rear panel label	

DEFAULT DISPLAY	☐ Default Display settings (TIME = 1:00, PRES = 250 mmHg) upon selection of default display (your institution may use different Default Display settings)
BATTERY CHARGED	☐ battery fully charged

Printed "Label" from Tourniquet Report Printer

6 Service Code Summary

WARNING: DO NOT service this equipment. If you require service, contact your Stryker sales representative or call Stryker customer service at 1-800-253-3210. Failure to comply may result in user/patient injury.

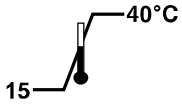
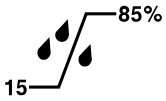
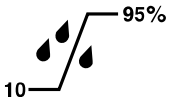
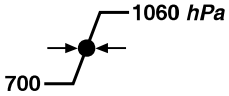
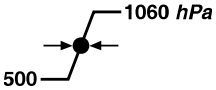
Service Alarms	Code	Description
CALIBRATION ERROR	30	Calibration test detects error.
REAL-TIME CLOCK STOPPED	31	Real-time clock has failed or stopped.
SERIAL INTERFACE ERROR	32	Serial interface fault.
FP NONVOLATILE MEMORY ERROR	33	The nonvolatile memory for the FP processor has failed a memory test.
FP FILES CORRUPT	34	The nonvolatile memory storing the FP code has failed a memory test.
A NONVOLATILE MEMORY ERROR	35	The nonvolatile memory for the A code has failed a memory test.
B NONVOLATILE MEMORY ERROR	36	The nonvolatile memory for the B code has failed a memory test.
HARDWARE FAULT	37	An internal hardware fault was detected.
POWER SUPPLY FAULT	38	Internal power supply circuit fault was detected.
BLADDER 1 LEAK	40	Bladder 1 leaks or is not operating correctly.
BLADDER 2 LEAK	41	Bladder 2 leaks or is not operating correctly.
VALVE OR AIR PUMP FAULT	42	Fault detected with the operation of the air valves or the air pump.

7 Specifications*

Model:	5920-011-000 SmartPump Dual Channel Tourniquet Pump
Size:	
Dimensions:	15.5 inch height x 10 inch width x 9 inch depth [39.4cm x 25.4cm x 22.9cm]; add 1.5 inch [3.8cm] for mounting pole at bottom; 1 inch [2.54cm] diameter roll stand pole mount
Weight:	
Unpackaged:	12.0 lbs [5.45 kgs]
Packaged:	18.25 lbs [8.28 kgs]
Equipment Type:	Class I, Defibrillation Proof Type BF Applied Part
Approvals	 48WJ CAN/CSA C22.2 No. 601.1 UL 60601-1 IEC 60601-1-2:2001 using IEC 61000-4-2, -3, -4, -5, -6, -8, -11; EN61000-3-2, -3; EN55011 level A/ CISPR 11 A emissions
Power Sources:	
AC Input:	100 - 240 VAC 50/60 Hz universal switching power supply Automatic internal battery switchover for AC–free use or AC loss protection
Facility power:	120 VAC, 10A, hospital grade receptacle
AC Input:	
Input voltage range:	100 – 240 VAC
Frequency:	50/60 Hz
AC fuses:	3.15A / 250V
Power requirements:	1.5 A @ 120 VAC
Internal DC Supply Module:	
Output voltage:	15 VDC ± 1%, 150 mV pk-pk ripple
Output current:	4A maximum
Output power:	60 W maximum
Overload protection:	short circuit, 110% - 150% auto recovery
Over voltage protection:	115% - 130% of rated output voltage
Internal Battery:	
Type:	nickel metal hydride (NiMH)
Nominal voltage:	12 VDC
Rated capacity:	2.6 Ahr
Over current protection:	integral PTC fuse
Over temperature sense:	integral thermistor
Charge time:	1 hour (80% charge), 6 hours (full charge)
Power conservation:	30 days (fully charged, then unplugged)
Display:	
Type:	High resolution backlit custom LCD
Timer:	Elapsed time numeric
Pressure:	Real-time digital numeric with graphic pressure gauge

*Specifications are approximate and may vary from unit to unit or as a result of power supply fluctuations.

7 Specifications

Air Pump:		
Nominal power:	12 VDC, 1.25 A	
Flow:	10 LPM open flow	
Pressure Transducers:		
Operating pressure:	0 – 15 psi	
Maximum pressure:	30 psi	
Repeatability:	± 0.2% FS typical	
Cuff Pressure:		
Accuracy:	± 2% or 4 mmHg, whichever is greater, set pressure value	
Range:	100 to 475 mmHg	
Cuff Timer:		
Range:	1 to 240 minutes	
Adjustment:	1 to 15 minutes – 1 minute increments; 15 to 240 minutes – 5 minute increments	
Quick Connect Hose Couplings	CPC PMC1602 or equivalent	
Environment	**Operation**	**Storage and Transportation**
Temperature:		
Relative Humidity:		
Atmospheric Pressure:		
Optional Printer Tray:		
Tray size:	8.25 inch width x 7.5 inch depth [21 cm x 19 cm]	
Tray load capacity:	5 lbs [2.3 kgs] maximum load capacity	
Pole, Basket and Stand:		
Pole:	adjustable height from 46 inch to 56 inch [117cm to 142cm]	
Base:	weighted base with 5 legs and heavy duty casters (two casters can be locked)	
Basket size:	6 inch height x 13 inch width x 8 inch depth [15.2cm x 33.0cm x 20.3cm]	
Basket load capacity:	5 lbs [2.3 kgs] maximum load capacity	

Electromagnetic Compatibility Information

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off (with AC power cord unplugged) and then on, the user is encouraged to try to correct the interference by one or more of the following measures:

- reorient or relocate the receiving device
- increase the separation between the equipment
- connect the equipment into an outlet on a circuit breaker different from that to which the other device(s) are connected
- consult the manufacturer or field service technician for help.

Only Stryker printer and shielded serial cable may be connected to the equipment's serial port. Usage of accessories or cables other than those sold by Stryker may result in increased RF emissions or decreased RF immunity of the equipment.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Dual Channel SmartPump is intended for use in the electromagnetic environment specified below. The customer or the user of the Dual Channel SmartPump should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Dual Channel SmartPump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The Dual Channel SmartPump is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Dual Channel SmartPump is intended for use in the electromagnetic environment specified below. The customer or the user of the Dual Channel SmartPump should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Dual Channel SmartPump, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended separation distance $d=1.67\sqrt{P}$ $d=1.67\sqrt{P}$ 80 MHz to 800 Mhz $d=2.33\sqrt{P}$ 800 MHz to 2.5 Ghz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Dual Channel SmartPump is intended for use in the electromagnetic environment specified below. The customer or the user of the Dual Channel SmartPump should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±2, 4, 6 kV contact ±2, 4, 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±1 kV for input/output lines	±0.5, 1 kV differential mode ±0.5, 1, 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle <40% U_T (>60% dip in U_T) for 5 cycles <70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 cycles	95% Reduction (10 ms) 60% Reduction (100 ms) 30% Reduction (500 ms) 95% Reduction (5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dual Channel SmartPump requires continued operation during power mains interruptions, it is recommended that the Dual Channel SmartPump be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the alternating current mains voltage prior to application of the test level.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Dual Channel SmartPump			
The Dual Channel SmartPump is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Dual Channel SmartPump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dual Channel SmartPump as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.70	1.11	2.21
100	11.70	3.50	7.00

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Stryker Instruments
4100 E. Milham
Kalamazoo, MI
(USA) 49001
1-269-323-7700
1-800-253-3210

2007/04 5920-011-700 Rev - www.stryker.com